

HW file

REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA:

KEY WORDS:

Reviewer Name: Ronald W. Steigerwalt, Ph.D. Pharmacology Team Leader

Division Name: Division of Metabolic and Endocrine Drug Products (DMEDP)

HFD#510

Review Completion Date: June 30, 1999

Review number: 1

IND/NDA NUMBER: NDA 21-117

Serial number/date/type of submission: 000, new NDA

Information to sponsor: Yes () No (X)

Sponsor (or agent): Abbott Hospital Products Division; One Abbott Park Road; Abbott Park, IL 60064-3500

DRUG 10% Calcium Chloride Injection, USP, Plastic Syringe

Chemical Name: $\text{CaCl}_2 \cdot \text{H}_2\text{O}$

Molecular Formula/ Molecular Weight: 110.99

Indication: Treatment of hypocalcemia

Clinical formulation: 10% solution in water.

Route of administration: IV

Proposed clinical protocol or Use: see above indications.

Previous clinical experience: Although this is currently deemed a "new drug", there has been extensive use since 1938. This product was grandfathered under the 1938 Food, Drug & Cosmetic Act in a glass container under the brand ABBOJECT®. The current NDA is for the same solution in plastic syringes.

INTRODUCTION AND DRUG HISTORY:

This product was grandfathered under the 1938 Food, Drug & Cosmetic Act in a glass container under the brand ABBOJECT®. The current NDA is for the same solution in plastic syringes. There has been extensive use in humans for many years. The current submission is to cover a new product in plastic syringes. The syringes are previously approved for use with other similar products.

Studies reviewed within this submission: Sponsor provided a literature search consisting primarily of clinical data. There are no preclinical studies needed to support the approval of this product since the solution has been on the market for a number of years. The syringe was previously approved for use with similar products.

RECOMMENDATIONS:

The labeling in the carcinogenicity and reproduction sections proposed by the sponsor is acceptable. No changes to the label are necessary from a pharmacology standpoint. Pharmacology recommends that this NDA be approved. There is no need for further action from pharmacology.

/S/

APPEARS THIS WAY
ON ORIGINAL

Ronald W. Steigerwalt, Ph.D.
Pharmacology Team Leader

cc: NDA Arch
HFD510
HFD510/Steigerwalt/McCort
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